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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,575	06/26/2003	Leonard M. Patt	480048.457	4943

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EXAMINER	
KOSAR, ANDREW D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/607,575	PATT, LEONARD M.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *4,5,9,10,13 and 31-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-8,11,12 and 14-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/14/03;1/9/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-30) and the species GHK:Cu(II) with hyaluronic acid, in the reply filed on February 1, 2006 is acknowledged.

Applicant's species is readable upon claims 1-3, 6-8, 11, 12 and 14-30.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4, 5, 9, 10, 13 and 31-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 1, 2006.

Claims 1-3, 6-8, 11, 12 and 14-30 have been examined on the merits.

In the interest of compact prosecution, and for Applicant's benefit, claims 4, 5, 9, 10 and 13 have been examined insofar as formal matters, double patenting and 35 USC § 112 1st and 2nd paragraphs. Inclusion does not imply or suggest the claims have been examined with respect to the prior art under 35 USC §§ 102 and/or 103.

Information Disclosure Statement

Applicant's IDS submissions (1/9/04 and 11/14/03) are acknowledged and have been considered.

References not in English have been considered insofar as they are discussed in the specification, or to the extent of the English abstract.

Reference AP (1/9/04) has been considered. The examiner has included a full copy of the article, cited on the instant PTO-892.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites 'modified form', which is vague and indefinite, as the specification and claims do not set forth how far one could 'modify' hyaluronic acid and still be within the scope of the claim. Furthermore, it is unclear how a 'modified hyaluronic acid' is a 'natural material'.

Claim 5 recites, "vegetable oil, lanolin, beeswax" which are natural products, not 'synthetic materials', and thus the claim lacks clear antecedent basis, as claim 4 only provides for 'synthetic materials'.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 6-8, 11, 12 and 14-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over MURAD (US Patent 6,071,541) in view of SIMÉON (A. Siméon, et al. J. Invest. Dermitol. (2000) 115, pages 962-968; Abstract PTO-1449: 1/9/04), CALLEGARO (US Patent 5,232,303 B1), RITTER (US Patent 6,086,863) DELLE VALLE (US Patent 5,925,626)and KUO (US Patent 6,096,727).

In view of the elected species, the instant claims are generally drawn to GHK:Cu(II) and hyaluronic acid in a composition.

Siméon teaches GHK:Cu(II) has, "previously shown to be an activator of wound healing." (Abstract). The GHK:Cu(II) was formulated in Dulbecco's PBS for *in vivo* usage (page 963, *Experimental Design*).

Murad teaches a composition (a "skin perfecting lotion") comprising hyaluronic acid, propylene glycol (an excipient), carbomer (a thickening agent), methylparaben (a paraben preservative), cetyl alcohol (an emulsifying agent; listed as cetaryl alcohol, which is a combination of cetyl alcohol and steryl alcohol), water (an inert and physiologically acceptable carrier or diluent). (Example 3, columns 13-14). A lotion can be any of a solution, thick solution, suspension or gel.

Callegaro teaches that hyaluronic acid is known for use in treating wounds (e.g. claim 35).

Ritter teaches a therapeutic composition of a microsphere encapsulated hyaluronic acid and a pharmaceutically acceptable carrier for promoting the healing of surgical wounds, pathogenic wounds, bone fractures, stasis ulcers and chronic wounds (e.g. claim 30).

della Valle teaches various compositions of hyaluronic acid for treating wounds (e.g. Examples 1-12, columns 11-12).

Kuo teaches a treating a wound with a sponge or gel comprising a modified hyaluronic acid.

The difference between that which is claimed, and that which is taught by the prior art, is that while both compounds are known to be used to treat wounds, they are not taught in the same composition.

As set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art."

In the instant case, both compounds, the GHK:Cu(II) of Siméon and the hyaluronic acid compositions of Callegaro, Ritter, della Valle and Kuo (lotion, sponge, gel, microsphere, injectable), are taught to be used in treating wounds, and thus it is *prima facie* obvious to prepare a third composition comprising both GHK:Cu(II) and hyaluronic acid for treating wounds.

Further, it would have been obvious to one skilled in the art at the time of invention to determine all optimum and operable conditions (e.g. ratios, concentrations of elements), because such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation. ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). *See* MPEP § 2145.05).

One would have been motivated to had adjusted the concentrations of the copper peptide and/or the soft tissue filler, in order to determine all optimum and operable conditions for treating wounds.

One would have had a reasonable expectation for success in making compositions with various concentrations of copper peptide and/or soft tissue filler, as such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1-3, 6-8, 11, 12 and 14-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over CARMICHAEL (US 2003/0134781 A1) in view of Siméon, Callegaro, della Valle, Ritter and Kuo, as applied to claims 1-3, 6-8, 11, 12 and 14-30 *supra*.

The applied reference has a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by:

(1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another";

(2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or

(3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c); or

(4) a showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The instant claims are presented *supra*. The teachings of Siméon, Callegaro, della Valle, Ritter and Kuo are presented *supra*.

Carmichael teaches a method of applying a composition comprising a copper peptide complex to the skin to treat hyperpigmentation (claim 1). The peptide:Cu is GHK:Cu(II) (claim 4), at ratios of 1:1 to 1:2 (or 1:3) (claims 5 and 6) and the peptide copper complex is at various % weight (claims 7-9), is encapsulated in a liposome or microsponge (claim 10). The composition further comprises various carriers (claim s 12 and 13), and ingredients e.g. preserving agents, a wax ester, etc. (claims 14-20), thickening agents, excipients, surfactants, etc. (claim 21) and the composition is in the form of a solution, cream, gel, fluid cream, lotion or oil (claim 22).

Although the claims of Carmichael are drawn to the method of use, the compounds are necessarily taught, as they are used in the method.

Furthermore, Examples 1, 3, 5 and 6 teaches specific compositions (paragraph [0055] to paragraph [0060]).

The difference between that which is claimed, and that which is taught by the prior art, is that while both compounds are known to be used to treat wounds, they are not taught in the same composition.

As set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art."

In the instant case, both compounds, the GHK:Cu(II), as taught by Siméon and the hyaluronic acid compositions of Callegaro, Ritter, della Valle and Kuo (lotion, sponge, gel, microsphere, injectable), are taught to be used in treating wounds, and thus it is *prima facie*

obvious to prepare a third composition comprising both GHK:Cu(II) and hyaluronic acid for treating wounds.

Further, it would have been obvious to one skilled in the art at the time of invention to determine all optimum and operable conditions (e.g. ratios, concentrations of elements), because such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation. ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). *See* MPEP § 2145.05).

One would have been motivated to had adjusted the concentrations of the copper peptide and/or the soft tissue filler, in order to determine all optimum and operable conditions for treating wounds.

One would have had a reasonable expectation for success in making compositions with various concentrations of copper peptide and/or soft tissue filler, as such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 14-18 and 20-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 18 and 22-33 of copending Application No. 11/204,772, in view of Siméon, Callegaro, della Valle, Ritter and Kuo, *supra*.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both 11/204,772 and the instant Application are drawn to compositions of copper peptides and hyaluronic acid. 11/204,772 teaches a composition of a copper peptide complex and hyaluronic acid (claim 23).

Furthermore, MPEP § 804 (II) states, "When considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the

claim of a patent, the disclosure of the patent may not be used as prior art. *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992). This does not mean that one is precluded from all use of the patent disclosure." (*emphasis added*). "Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970)." In the instant case Example 5, which provides support for the patent claims, specifically embodies a copper peptide complex and modified hyaluronic acid in isotonic saline for injection.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-42 of copending Application No. 10/627,193, in view of Siméon, Callegaro, della Valle, Ritter and Kuo, *supra.*

Claims 1-3, 6-12 and 14-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17, 19-28 and 30 of copending Application No. 10/264,427, in view of Siméon, Callegaro, della Valle, Ritter and Kuo, *supra.*

Claims 1-12 and 14-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/264,392, in view of Siméon, Callegaro, della Valle, Ritter and Kuo, *supra.*

Claims 1-12 and 14-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 10/264,363, in view of Siméon, Callegaro, della Valle, Ritter and Kuo, *supra*.

Because the rejections are all predicated upon the same secondary references and the same reasoning, the rejection has been set forth once, where the teachings of each patent application is presented sepately.

Although the conflicting claims are not identical, they are not patentably distinct from each other because each Application listed above and the instant Application claims are drawn to compositions of copper peptides.

The teachings of Siméon, Callegaro, della Valle, Ritter and Kuo are presented *supra*.

10/627,193 teaches copper peptide complexes including GHK:Cu (claim 20), AHK, LHK:Cu (claim 21), GHK-R:Cu (claim 22), Cu:peptide ratio of 1:1 to 2:1 (or 3:1) (claims 23 and 24), the peptide is in various concentrations (claim 25-28), and comprises additional elements, including various carriers and is formulated in different forms (claims 29-42).

10/264,427 teaches compositions comprising copper peptide complexes and in the form of a gel, lotion, cream, liquid, emulsion or microemulsion (e.g. claims 1-17 and 19-30, esp. claims 20-23 and 30).

10/264,392 teaches compositions comprising a copper peptide complex, e.g. GHK:Cu(II), at various % composition, and a method of using specific formulations (claims 1-23). Although the claims are drawn to a method of use, the products used necessarily teach the instant products.

10/264,363 teaches compositions comprising a copper peptide complex, e.g. GHK:Cu(II), at various % composition, and ratios, as well as compositions with additional elements (claims 1-27).

The difference between that which is claimed in the Applications listed above and the instant claims, is that the instant claims further comprise hyaluronic acid.

As set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art."

In the instant case, both compounds, the GHK:Cu(II) of 10/627,193 and the hyaluronic acid compositions of Callegaro, Ritter, della Valle and Kuo (lotion, sponge, gel, microsphere, injectable), are taught to be used in treating wounds, and thus it is *prima facie* obvious to prepare a third composition comprising both GHK:Cu(II) and hyaluronic acid for treating wounds.

Further, it would have been obvious to one skilled in the art at the time of invention to determine all optimum and operable conditions (e.g. ratios, concentrations of elements), because such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation. ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). *See* MPEP § 2145.05).

One would have been motivated to had adjusted the concentrations of the copper peptide and/or the soft tissue filler, in order to determine all optimum and operable conditions for treating wounds.

One would have had a reasonable expectation for success in making compositions with various concentrations of copper peptide and/or soft tissue filler, as such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

The examiner has identified five copending Applications which have been rejected under Double Patenting above. Because of Applicant's prolific Patent and Application portfolio, the burden is shifted to Applicant to identify all relevant Applications and Patents and to included said Applications and Patents on any terminal disclaimer filed.

Inventorship / Ownership

Claims 1-12 and 14-30 are directed to an invention not patentably distinct from claims 1-23 of commonly assigned 10/264,392, for the reasons set forth above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300).

Commonly assigned 10/264,392, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at

the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Conclusion

NO CLAIMS ARE ALLOWED.

The prior art made of record on the attached PTO-892 and not relied upon in any rejection is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Andrew D. Kosar, Ph.D.
Art Unit 1654

4/13/06
ANISH GUPTA
PRIMARY EXAMINER